K133644
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510(k) Summary

as required by 21 CFR Part 807.87(h)

FEB 25 2014

Identification of the Submitter

Submitter:	M. Alaine Medio, RAC PET and PCS Regulatory Projects Manager Siemens Medical Solutions USA, Inc. Molecular Imaging 810 Innovation Drive Knoxville, TN 37932
Telephone Number:	(865)218-2703
Fax Number:	(865)218-3019
Name / Address of Manufacturer	Siemens Medical Solutions USA, Inc Molecular Imaging 2501 N. Barrington Road Hoffman Estates, IL 60192 USA
Date of Submission:	November 25, 2013

Identification of the product

Device Proprietary Name:	*syngo*.via MI Workflows
Common Name:	Image Processing Software
Classification Name:	Picture Archiving and Communication System per 21 CFR 892.2050
Product Code:	LLZ
Classification Panel:	Radiology
Device Class:	Class II

Marketed Devices to which Equivalence is claimed

Device	Manufacturer	510(k) Number
syngo.via MI Workflows	Siemens Medical Solutions USA, Inc	K123577 (January 22, 2013)

Device Description:

The *syngo*.via MI Workflows are software only medical devices which will be delivered on CD-ROM / DVD to be installed onto the commercially available Siemens *syngo*.via software platform by trained service personnel.

syngo.via MI Workflows are medical diagnostic applications for viewing, manipulation, 3D-visualization and comparison of medical images from multiple imaging modalities and/or multiple time-points. The application supports functional data, such as PET or SPECT as well as anatomical datasets, such as CT or MR. The images can be viewed in a number of output formats including MIP and volume rendering.

syngo.via MI Workflows enable visualization of information that would otherwise have to be visually compared disjointedly. *syngo*.via MI Workflows provide analytical tools to help the user assess, and document changes in morphological or functional activity at diagnostic and therapy follow-up examinations. They additionally support the interpretation and evaluation of examinations and follow up documentation of findings within healthcare institutions, for example, in Radiology (Oncology), Nuclear Medicine and Cardiology environments.

The modifications to the *syngo*.via MI Workflows (K123577) is adding a new feature allowing the physician to harmonize SUV data based on a standard reference value, allowing comparison of scans acquired over multiple timepoints or using different scan parameters or equipment. This change is based on current commercially available software features and does not change the technological characteristics of the device.

syngo.via MI Workflows are intended to be run on the Siemens *syngo*.via software platform (K123375) either alone or with other advanced commercially cleared applications.

Safety and Effectiveness:

The device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of the device.

Risk Management has been ensured via risk analyses in compliance with ISO 14971:2012 to identify and provide mitigation to potential hazards beginning early in the design cycle and continuing throughout the development of the product. Siemens Medical Solutions, USA Inc. adheres to recognized and established industry standards for development including ISO 13485 and IEC 62304.

Verification and Validation activities have been successfully performed on the software package, including assurance that functions work as designed and that all hazard mitigations have been fully implemented.

Indications for Use:

syngo.via MI Workflows are medical diagnostic applications for viewing, manipulation, 3D-visualization and comparison of medical images from multiple imaging modalities and/or multiple time-points. The application supports functional data, such as PET or SPECT as well as anatomical datasets, such as CT or MR.

syngo.via MI Workflows enable visualization of information that would otherwise have to be visually compared disjointedly. *syngo*.via MI Workflows provide analytical tools to help the user assess, and document changes in morphological or functional activity at diagnostic and therapy follow-up examinations. *syngo*.via MI Workflows can perform harmonization of SUV(PET) across different PET systems or different reconstruction methods.

syngo.via MI Workflows support the interpretation and evaluation of examinations and follow up documentation of findings within healthcare institutions, for example, in Radiology, Nuclear Medicine and Cardiology environments.

Note: The clinician retains the ultimate responsibility for making the pertinent diagnosis based on their standard practices and visual comparison of the separate unregistered images. *syngo*.via MI Workflows are a complement to these standard procedures.

Conclusions:

There are no differences in the Fundamental Technological Characteristics of the *syngo*.via MI Workflows as compared to the currently commercially available software (K123577). Additionally, there have been no changes that raise any new issues of safety and effectiveness as compared to the predicate device. Based on this information, as well as the documentation in support of the modifications, it is Siemens opinion that the *syngo*.via MI Workflows software with the modifications outlined in this application is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 25, 2014

Siemens Medical Solutions USA, Inc.
% Alaine Medio, RAC
PET and PCS Regulatory Projects Manager
810 Innovation Drive
KNOXVILLE TN 37932-2571

Re: K133644
Trade/Device Name: *syngo.via* MI Workflows
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving and Communications System
Regulatory Class: II
Product Code: LLZ
Dated: November 26, 2013
Received: November 27, 2013

Dear Ms. Medio:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

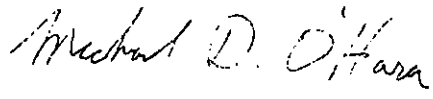
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K133644

Device Name: *syngo.via* MI Workflows

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Michael D. O'Hara

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) K133644